

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA**

IN RE MYLAN N.V.
SECURITIES LITIGATION

Master File No. 2:20-cv-00955-NR

CLASS ACTION

Electronically Filed

**LEAD PLAINTIFF'S MOTION TO CLARIFY THE COURT'S
MAY 18, 2023 OPINION ON DEFENDANTS' MOTION TO DISMISS**

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I. INTRODUCTION

This Motion for Clarification seeks to resolve a disagreement between the parties about the scope of liability under Rule 10b-5(a) and (c), and the Court’s holding on Defendants’ Motion to Dismiss. The Complaint alleges that Defendants orchestrated a “pervasive, top-down scheme to dupe the FDA and ignore regulatory compliance best practices in the name of juicing manufacturing output and increasing corporate profits.” *In re Mylan N.V. Sec. Litig.*, 2023 WL 3539371, at 18 (W.D. Pa. May 18, 2023). Based on those allegations, the Complaint asserts, among other claims, (1) a misrepresentation claim challenging certain of Defendants’ public statements as false and misleading under Rule 10b-5(b), and (2) a scheme liability claim challenging Defendants’ acts as deceptive and manipulative under Rule 10b-5(a) and (c). On May 18, 2023, the Court issued an opinion in which it sustained the misrepresentation claim as to one actionable statement (namely, Mylan’s blanket denial in January 2019 that Mylan employees deceived the FDA), and sustained the scheme liability claim.

After failing to initially move to dismiss the scheme claim at all, Defendants have now taken the position that the sustained scheme claim is “entirely derivative” of the sustained misrepresentation claim, and that as such, the scheme claim consists entirely of a single misstatement. But decades of Supreme Court precedent have made it “crystal clear that a misrepresentation need not be involved [in a claim] based on Rule 10b-5(a) or (c).” *In re Enron Corp. Sec., Deriv. & ERISA Litig.*, 235 F. Supp. 2d 549, 585 (S.D. Tex. 2002) (citing *SEC v. Zandford*, 535 U.S. 813 (2002)). Further, courts within the Third Circuit have repeatedly held that a scheme claim under Rule 10b-5(a) or (c), **cannot** be based solely on a misstatement. *De Vito v. Liquid Holdings Group, Inc.*, 2018 WL 6891832, at *42 (D.N.J. Dec. 31, 2018) (collecting cases). Accordingly, Defendants are misreading the court’s opinion, which is the reason for this Motion for Clarification.

Lead Plaintiff respectfully submits that clarification of the Court’s opinion is necessary to help guide the parties in this important litigation going forward. Defendants refuse to engage in discovery (including exchanging mandatory initial disclosures) in this already long-pending case, asserting that they intend to file *another* motion seeking dismissal. Defendants attempt to justify their refusal to engage in discovery by incorrectly contending, based on their misreading of the opinion, that their forthcoming motion under Rule 12(c) will be “case dispositive”—presumably arguing that there is no loss causation for the sole remaining 10b-5(b) misstatement in the case. However, *all* of the corrective disclosures remain in this case under a proper legal analysis of the scope of the scheme claim that was sustained 10b-5(a) and (c). Moreover, Defendants have made clear that they do not anticipate that this case will *ever* move into fact discovery, but that even if it does, they intend to radically narrow its scope based on their misreading of the Court’s opinion.

Lead Plaintiff respectfully requests that this Court clarify that its opinion sustained the scheme claim as pled in the Complaint, and that it did not, as Defendants suggest, intend to contravene well-established binding precedent by sustaining a scheme claim based only on a single misstatement.

II. RELEVANT BACKGROUND¹

The Complaint challenges a years-long scheme through which Defendants concealed from the FDA and investors Mylan’s systemic violations of key FDA regulations governing product quality and safety, including at the Company’s flagship drug manufacturing facility in Morgantown, West Virginia. ¶1. The Complaint alleges that Defendants’ fraudulent scheme began

¹ Given the Court’s familiarity with the facts of this case, this motion highlights only those facts that are most pertinent to Lead Plaintiff’s scheme claim. References to “¶__” are to the Consolidated Class Action Complaint filed on November 13, 2020. ECF No. 39. Unless otherwise indicated, all internal citations and quotations marks are omitted.

no later than February 2016 – the start of the Class Period – by which time Defendants were directing pervasive acts of data fraud on a global scale in order to conceal major violations of federal drug manufacturing standards at its key plants from regulators and the public, including investors. In furtherance of this scheme, Defendants directed Mylan’s employees to “invalidat[e] failing test results,” “deliberately corrupt[] data files and crash[] computers” to avoid recording data that reflected failing results, “alter[] drug samples,” and “falsif[y] evidence of CGMP remediation.” *E.g.*, ¶¶13, 82, 86, 93, 118, 120. Indeed, as a Mylan whistleblower told the FDA in mid-2015 – months before the start of the Class Period – Mylan’s Indian operations were rife with egregious CGMP violations and data fraud aimed at concealing them, and that Mylan’s research and development center in Hyderabad “had become a hub for data fraud that had disseminated its methods of falsification throughout Mylan’s Indian operations.” *E.g.*, ¶85.

A few months later, in November 2016, the FDA warned Defendants that Mylan’s manufacturing plant in Morgantown, West Virginia – the heart of the Company’s U.S. operations – was also riddled with severe violations of FDA-mandated quality and safety standards, including a host of improper conduct purposely designed to bypass Mylan’s quality systems and controls. ¶1. Knowing that compliance with these regulations was critically important to the market, Defendants continued to conceal and misrepresent the full extent of Mylan’s regulatory failures from the FDA and the market by, among other things, issuing a “façade of documents” to create the appearance of compliance in order to fend off the agency. ¶12. As a result of this continuing fraudulent scheme, product quality further deteriorated rather than improving. *Id.*

The truth first began to emerge on June 28, 2018, when *Bloomberg* leaked news of the results from the FDA’s 2018 investigation into Mylan’s data integrity and quality control failures. ¶16. The investigation had uncovered, among other things, Mylan’s improper practice of

invalidating failing results and re-testing drug products without adequate investigation. ¶13. Disclosures made on August 8, 2018, and February 26, 2019, revealed additional details about Defendants' scheme. ¶¶17-18. Defendants tried to mitigate the impact of these disclosures, including in a materially false and misleading statement published in *Bloomberg* on January 31, 2019. ¶299. The full extent of Defendants' fraud came to light on May 7, 2019, when Mylan reported a surprise loss due, in part, to additional costs associated with the extensive remediation efforts at the Morgantown facility. ¶19. As a result of these disclosures, the price of Mylan common shares declined by approximately 50%, erasing billions in shareholder value. ¶¶17-19, 330.

On May 18, 2023, this Court issued an opinion resolving Defendants' Motion to Dismiss the Complaint. *Mylan*, 2023 WL 3539371. The Court's opinion sustained the Complaint's (1) misrepresentation claim under Rule 10b-5(b) as to Defendants' January 31, 2019, statement, and (2) scheme claim under Rules 10b-5(a) and (c) as to Defendants' fraudulent scheme to conceal Mylan's serious regulatory violations by committing pervasive data fraud. Unlike the misrepresentation claim, the scheme claim does not require the Court to find that *any* of the statements are actionable under Rule 10b-5(b). In sustaining the scheme claim, this Court faithfully applied Supreme Court precedent, which makes clear that there need *not* "be a specific oral or written statement before there could be [scheme] liability" because "[c]onduct itself can be deceptive" and thus is independently actionable. *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 158 (2008); *see also Enron*, 235 F. Supp. 2d at 585 (courts have "made crystal clear that *a misrepresentation need not be involved* and that a suit could be based on Rule 10b-5(a) or (c)") (emphasis added).

As the Complaint alleges, the scheme claim is predicated on the “deceptive or manipulative act[s]” that Defendants committed “in furtherance of the alleged scheme to defraud.” *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, 2020 WL 3026564, at *16 (D.N.J. June 5, 2020). These acts included, among other things, “manipulating drug test results,” improperly “testing into compliance,” “falsifying root cause reports, crashing computer systems, and altering drug sample sets,” ¶¶6, 49, 255, which Defendants committed in furtherance of their scheme to deceive the FDA and the market about the extent of Mylan’s systemic and egregious regulatory violations, ¶¶1, 328; *see infra* Section III.B. As alleged in the Complaint, the Class Period for the scheme is February 16, 2016, to May 17, 2019, inclusive.²

In the course of the parties’ Rule 26(f) discussions, Defendants have made clear that they believe that the scheme claim is coextensive with the misrepresentation claim, and that they are entitled to dismissal of both claims. But Defendants’ assertion is predicated on their misreading of the opinion as having disregarded binding Supreme Court precedent. *See* Ex. A (Defs.’ Draft 26(f) Report) at 3 (characterizing scheme claim as limited to “a single actionable statement” despite well-pled allegations of deceptive and manipulative acts). Defendants’ misreading is already dramatically impacting the prosecution of this case. They have refused to engage in *any* discovery on the grounds that they intend to file *another* motion to dismiss the case, this time under Rule

² The Complaint includes allegations from numerous FEs, who confirmed that Defendants’ deceptive or manipulative acts certainly date back to February 16, 2016, and potentially pre-date the alleged Class Period. *E.g.*, ¶¶110-15, 241. Courts have recognized that in scheme liability cases, plaintiffs are unlikely to know the exact dates of defendants’ deceptive or manipulative acts without discovery. *See, e.g., In re Blech Sec. Litig.*, 928 F. Supp. 1279, 1290-91 (S.D.N.Y. 1996) (“Unlike most fraud—most notably misrepresentation claims . . . —where at least some aspects of the time, place, and other details of a defendant’s activity are within the knowledge of the plaintiff as a matter of course—[scheme] claims present circumstances in which the mechanism of the scheme is likely to be unknown to the plaintiffs.”), *class cert. granted*, 187 F.R.D. 97, 100 (S.D.N.Y. 1999). The parties will have ample opportunities to address issues concerning the appropriate Class Period at the class certification stage, after they have undertaken discovery.

12(c). Defendants claim that discovery should be indefinitely frozen (notwithstanding the nearly three-year discovery stay that was only recently lifted) because their forthcoming Rule 12(c) motion will supposedly be case dispositive, presumably arguing that there is no loss causation for the sole remaining 10b-5(b) misrepresentation.

Moreover, Defendants have asserted that *if* discovery commences, they will dramatically narrow it and will refuse to produce documents and testimony concerning, e.g., the “practices at Mylan that the Complaint pleads were deceptive or manipulative”—i.e., the conduct underlying the scheme claim. Ex. A (Defs.’ Draft 26(f) Report) at 3. Notably, this conduct also underlies Lead Plaintiff’s sustained misrepresentation claim because the actionable misrepresentation states broadly that Mylan employees *never* “circumvented data and quality systems,” in response to *Bloomberg*’s equally broad investigation into the Company’s practices—meaning that Mylan’s history of engaging in conduct that “circumvented data and quality systems” is directly relevant to falsity, among other things. *See also Mylan*, 2023 WL 3539371, at *18 (finding, among other things, the alleged “pervasive, top-down scheme to dupe the FDA and ignore regulatory compliance best practices in the name of juicing manufacturing output and increasing corporate profits” relevant to scienter). Accordingly, discovery for the misrepresentation and scheme claims will encompass many of the same topics.

Lead Plaintiff understands the Court’s opinion to sustain the scheme claim as it was pled in the Complaint and to be consistent with Supreme Court and Third Circuit precedent. The opinion dismissed certain statements as inactionable under Rule 10b-5(b), but did *not* dismiss any of Defendants’ deceptive *conduct* under Rule 10b-5(a) or (c). Nor did Defendants even argue for such a result, as set forth below. In light of the parties’ disagreement, this motion seeks to clarify that the opinion sustained the scheme claim as pled in the Complaint.

III. ARGUMENT

“Although no Federal Rule of Civil Procedure specifically governs ‘motions for clarification,’ these motions are generally recognized and allowed by federal courts.” *Trinity Indus., Inc. v. Greenlease Holding Co.*, 2016 WL 4009546, at *2 (W.D. Pa. July 27, 2016). Courts have issued clarifications where, as here, “[t]he parties disagree as to the scope of the court’s holding in its opinion[.]” *J.J. Powell, Inc. v. U.S.*, 130 Fed. Cl. 410 (2016). Clarification is “appropriate” even when the requested “clarification is consistent with [the Court’s] opinion, and does not affect its prior analysis.” *Matthews Int’l Corp. v. Lombardi*, 2021 WL 9569378, at *1 (W.D. Pa. Mar. 9, 2021) (Ranjan, J.).

As detailed below, Lead Plaintiff’s requested clarification is consistent with the opinion, which denied Defendants’ motion to dismiss the scheme claim.

A. Clarification Is Appropriate in Light of the Parties’ Disagreement

The Court denied Defendants’ motion to dismiss the scheme claim. Defendants did not challenge the scheme claim in their opening brief and, on reply, presented only a narrow argument, which mischaracterized the scheme claim as coextensive with the alleged misrepresentations. The Court rejected that argument. *Mylan*, 2023 WL 3539371, at *19-20. The Court’s holding is plainly correct, as no actionable misstatements are required to state a claim for scheme liability. Any ambiguity resulted from Defendants’ decision not to address the scheme claim until their reply.

Accordingly, and in light of the parties’ disagreement, clarification is appropriate. Lead Plaintiff respectfully requests that the Court clarify that the opinion sustained (1) the misrepresentation claim as to Defendants’ statement published on January 31, 2019, in *Bloomberg*, and (2) the scheme claim as alleged in the Complaint.

B. The Requested Clarification Accords with the Opinion

The scheme claim is *not*, as Defendants argued, “entirely derivative of the misrepresentation claim,” and the opinion never concludes that it is. *Mylan*, 2023 WL 3539371, at *20. Even so, Defendants now suggest that the opinion contravenes precedent from the Supreme Court and courts around the country, which have consistently held that scheme liability does not require “a specific oral or written statement” because “[c]onduct itself can be deceptive.” *Stoneridge*, 552 U.S. at 158. These courts have made it “crystal clear that a misrepresentation need not be involved [in a claim] based on Rule 10b–5(a) or (c),” *Enron*, 235 F. Supp. 2d at 585, and have thus held that “deceptive conduct in the absence of ‘specific oral or written statement’ may create primary liability under Section 10(b),” *SEC v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 354 (D.N.J. 2009) (quoting *Stoneridge*, 552 U.S. at 158 (“erroneous” to hold that “there must be a specific oral or written statement before there could be liability under § 10(b) or Rule 10b-5.”)).

A complaint “state[s] a valid claim for ‘scheme liability’ under Rule 10b-(a) or (c)” as long as it adequately alleges “(1) that the defendant committed *a deceptive or manipulative act*, (2) in furtherance of the alleged scheme to defraud, (3) with scienter, and (4) reliance.” *Cognizant*, 2020 WL 3026564, at *16 (emphasis added). “These provisions capture a wide range of conduct.” *Lorenzo v. SEC*, 139 S. Ct. 1094, 1101 (2019) (discussing Rule 10b-5(a) and (c)).³

The opinion’s denial of Defendants’ motion to dismiss the scheme claim is further bolstered by the *Able Laboratories* case, which both parties cited in briefing Defendants’ motion. *In re Able Labs. Sec. Litig.*, 2008 WL 1967509 (D.N.J. Mar. 24, 2008); ECF No. 46 at 30 (citing

³ See also *In re CytRx Corp. Sec. Litig.*, 2015 WL 5031232, at *12 (C.D. Cal. July 13, 2015) (“While the purported scheme certainly involved allegedly false and misleading statements, it also included conduct beyond said statements, including the hiring of promoters, planning and editing well-timed article releases with targeted content to artificially inflate the value of company stock and raise revenue, and covering up the Company’s involvement.”).

Able Laboratories); ECF No. 48 at 60 (citing *Able Laboratories* in discussion of scheme claim). In *Able Laboratories*, a district court in this Circuit sustained a scheme claim based on alleged “manipulative and deceptive conduct” that is nearly identical to the conduct at issue in this case. 2008 WL 1967509, at *19-22. As here, the complaint in *Able Laboratories* alleged that defendants “falsified test results, tampered with computer data, forged records, and fabricated in house test data to meet FDA standards,” and thereby “effectuated the continued manufacturing and distribution of [the defendant’s] products, while concealing its noncompliance with FDA regulations.” 2008 WL 1967509, at *21 (cleaned up). “Defendants’ intentional concealment of their continuing FDA violations . . . caused Plaintiff (and others similarly situated) to suffer significant losses when Defendants’ conduct was revealed and the price of [the company’s] stock collapsed.” *Able Labs.*, 2008 WL 1967509, at *3. The *Able Laboratories* court held that these conduct-based allegations adequately pled “that [defendants] engaged in manipulative conduct in furtherance of a scheme to defraud in violation of Rule 10b-5(a) and (c).” 2008 WL 1967509, at *22.

So too here. The scheme claim is based on the Complaint’s extensive allegations detailing specific instances of Defendants’ manipulative and deceptive conduct. To name a few, Defendants engaged in “the unjustified invalidation of failing test results,” *e.g.*, ¶13, “deliberately corrupted data files and crashed computers” to avoid recording data that reflected failing results, *e.g.*, ¶¶86, 93, 118, committed “data fraud” and deployed “methods of falsification throughout Mylan’s Indian operations,” *e.g.*, ¶85, “altered drug samples,” *e.g.*, ¶82, and “falsif[ied] evidence of CGMP [i.e., Current Good Manufacturing Practice regulations enforced by the FDA] remediation,” *e.g.*, ¶120. Defendants’ manipulative conduct is nearly identical to the conduct that gave rise to a scheme claim in *Able Laboratories*, and it served the exact same purpose—“effectuat[ing] the

continued manufacturing and distribution of [Mylan's] products, while concealing its noncompliance with FDA regulations." 2008 WL 1967509, at *21; *see* ¶1 ("This case arises from Defendants' concealment of Mylan's systemic and egregious violations of key FDA regulations[.]").

<i>Able Laboratories</i>	<i>Lead Plaintiff's Complaint</i>
falsified drug quality test results	manipulating drug test results to achieve passing quality control results (¶6)
tampered with computer data regarding drug quality testing	corrupted data files and crashed computers to avoid recording failing results (¶86)
forged drug quality records	misreported the data relating to failing test results (¶100) and shredded data and quality control records (¶103)
fabricated in house test data to meet FDA standards	asked employees to falsify evidence of CGMP remediation (¶120)

Moreover, Defendants' interpretation of the opinion as sustaining the scheme claim only insofar as it is predicated on the January 31, 2019, statement in *Bloomberg* is inconsistent with ample case law from courts in the Third Circuit, which have repeatedly held that a scheme claim **cannot** be limited solely to actionable misstatements. *See, e.g., De Vito*, 2018 WL 6891832, at *42 (collecting cases showing that "courts within this Circuit have consistently required that a subsection (a) or (c) claim encompass deceptive conduct that goes beyond a material misstatement or omission"); *see also SEC v. Rio Tinto plc*, 41 F.4th 47, 53-54 (2d Cir. 2022) (reaffirming that "misstatements and omissions alone" cannot "form the basis for scheme liability" because in *Lorenzo*, the act of "dissemination" was the "something extra that makes a violation a scheme"). Defendants' interpretation is thus incorrect as a matter of law.

C. Defendants Waived Arguments as to the Scope of the Scheme Claim

Defendants had many opportunities to address the scheme claim in connection with their Motion to Dismiss, but they failed to do so. In their reply brief, Defendants made "a strategic

choice” to ignore applicable precedent and mischaracterize the scheme claim as entirely derivative of the misrepresentation claim. *NVR, Inc. v. Majestic Hills, LLC*, 2023 WL 3726895, at *1 (W.D. Pa. May 30, 2023) (Ranjan, J.). As this Court has previously explained, “Defendants’ refusal to raise [an] argument at the proper time reveals a strategic choice,” and “[t]hat is fine; but a party’s reconsideration of a strategic decision is not excusable neglect or good cause to get a ‘do-over.’” *Id.* Defendants “failed in [their] first effort to persuade the [Court] to dismiss” the scheme claim, and are not entitled to “simply change[] theories and tr[y] again.” *Newspaper, Newsprint, Mag. & Film Delivery Drivers, Helpers, & Handlers, Int’l Bhd. of Teamsters, Loc. Union No. 211 v. PG Publ’g Co.*, 2019 WL 9101872, at *2 (W.D. Pa. Dec. 27, 2019) (Ranjan, J.) (quoting *Bhatnagar v. Surrendra Overseas Ltd.*, 52 F.3d 1220, 1231 (3d Cir. 1995)).

Defendants’ Opening Brief did not address the scheme claim *at all*, *see* ECF No. 46, even though the Complaint clearly asserted one, ¶346 (quoting Rule 10b-5(a) and (c)). After Lead Plaintiff pointed out that Defendants’ “failure to even address this claim warrants denial of their motion,” ECF No. 48 at 60, Defendants addressed the scheme claim in a single sentence in their reply, arguing, “Plaintiff has failed to allege an actionable misrepresentation or scienter, and therefore has not alleged any deceptive conduct,” ECF No. 54 at 30. This argument is wrong as it fails to address the fact that “conduct-based claims ‘are viewed as distinct from claims under subsection (b) because the former make *deceptive conduct* actionable, as opposed to . . . deceptive statements.’” ECF No. 48 at 60 (emphasis added) (quoting *Cognizant*, 2020 WL 3026564, at *18). Defendants’ argument also disregards the opposition’s citation to “Defendant’s *acts* in furtherance of Mylan’s deceptive course of conduct.” *Id.* (citing ¶¶42, 66-77, 87-88, 121, 129, 132, 150, 186-87, 200).

During oral argument, Defendants passed up another opportunity to address the scheme claim. After the Court observed that the issue “wasn’t really briefed by both sides really all that extensively,” Ex. B (Hr’g Tr.) at 59:17-22 (Mar. 14, 2023), counsel for Lead Plaintiff explained that the scheme claim challenges “a course of conduct of fraudulent acts,” *id.* at 60:10-19 (citing *Able Labs.*, 2008 WL 1967509). Counsel for Lead Plaintiff further explained that Defendants’ deceptive conduct, including, among other things, “the destruction and shredding of documents,” “retesting without records,” and “pulling out power cords,” was “designed not just to deceive investors, but the FDA as well,” and thus formed the basis of “a pretty strong case for scheme liability.” Ex. B (Hr’g Tr.) 60:20-61:2. Counsel for Defendants failed to address these arguments. Instead, they reiterated their factually and legally incorrect argument that the scheme claim is “predicated on the same false and misleading statement[s] as its 10b-5(b) claim.” *Id.* at 68:10-69:4 (“refer[ring] the court to defendant’s reply brief at page 30”).

Defendants’ refusal to raise any argument addressing the **conduct** underlying the scheme claim “reveals a strategic choice,” *NVR*, 2023 WL 3726895, at *1, to rely solely on their incorrect argument that the scheme claim is “entirely derivative of the misrepresentation claim,” *Mylan*, 2023 WL 3539371 at *20. Defendants were entitled to make this choice, but now, they are not entitled to a “do-over.” *NVR*, 2023 WL 3726895, at *1 (refusing to entertain arguments that defense counsel failed to make after, during “oral argument on the [motion], the Court explicitly asked defense counsel” about the issue). Defendants thus have forfeited any argument that they failed to raise at the “proper time.” *Id.*⁴

⁴ Despite this fact, Defendants have indicated that they “intend to file a Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure 12(c).” Ex. A (Defs.’ Draft 26(f) Report) at 2. In order to file a Rule 12(c) motion, however, Defendants must first file their answer, which is due on July 14, 2023. At a minimum, deciding the scope of the sustained scheme claim will

IV. CONCLUSION

For the foregoing reasons, Lead Plaintiff respectfully requests that this Court clarify that the opinion denied Defendants' motion to dismiss the scheme claim, and sustained the scheme claim as pled.

Dated: June 20, 2023

Respectfully submitted,

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inform Defendants' answer to the Complaint, and may well obviate the need for additional motion practice, including a Rule 12(c) motion.

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